PRINT VERSION (pdf file - requires Adobe Acrobat)

PEC Update Home
PEC Home

The Department of Defense Pharmacoeconomic Center
PEC UPDATE
February 2003, Vol. 03, Issue 4, www.pec.ha.osd.mil

In This Issue . . .

1 Next Page

Editorial: Thoughts from the TRICARE Conference, Among Other Things

CAPT Joe Torkildson reflects on a basic requirement for successful problem-solving: buying in to the concept that the problem is 1) fixable, and 2) yours to fix.

2

Update on DoD Procurement Initiatives for Pharmaceuticals

What's going on with DoD and DoD/VA procurement initiatives (e.g., contracting actions, blanket purchase agreements) in various drug classes.

3

Barb's Barbs: Technological Evaluation of the PEC Staff

Barb lampoons us! Ouch!

4

New Drug Watch

New drugs, new devices, new indications, new guidelines, and other nuggets of information from Angela Allerman at the PEC:

- A new triptan (there are now seven), a new subcutaneous TNF inhibitor for rheumatoid arthritis, a new IV/IM biologic for severe psoriasis, a second testosterone gel product for hypogonadism, and a few new extended release formulations.
- Also, an insulin pen for kids, an OTC HbA1c testing device, and a number of new indications for existing drugs.
- Plus new evidence-based guidelines for lung cancer from the American College of Chest Physicians, guidelines for non-occupational post-exposure prophylaxis of HIV from the State of Rhode Island,

Last Issue

CDC adult immunization recommendations, and the CDC's comprehensive smallpox vaccination website.

- AND a few other items, including the recently-halted SMART Trial (Salmeterol Multi-Center Asthma Research Trial). Whew.

5

PDTS Corner

Update on the Pharmacy Data Transaction Service

Prescription Workload Trends - COL (Ret) Roger Williams looks at prescription workload volume for the Military Health System as a whole and for MTFs in each of the Services, split by beneficiary age (under 65 vs. 65 or older). The bottom line:

- Workload in the retail network and mail order continues to rise. In mail order, this is basically due to beneficiaries age 65 or older; in retail, workload in both age groups is on a steady rise.
- Overall, MTF workload is on an **upward** slope, an increase that appears to be coming from beneficiaries under 65. Utilization by beneficiaries age 65 or older is holding steady.
- The workload trends for individual Services mirror the trend of MTFs as a whole.

6

Special Note: 2003 DoD Pharmacoeconomics and Pharmacy Benefit Conference

The Department of Defense Pharmacoeconomics and Pharmacy Benefit Conference was held January 12-15, 2003 in San Antonio, Texas. Eighty-seven physicians, pharmacists, and nurses from the Army, Navy, and Air Force attended the 3-day conference to hear speakers from DoD, the Department of Veterans Affairs, and the Joint Commission on the Accreditation of Healthcare Organizations. Topics included evidence based medicine, outcomes research, pharmacoepidemiology, VA outcomes research programs, adverse drug reactions, JCAHO requirements, and research funding opportunities.

Slide sets and/or handouts for the following presentations are available on the PEC website at

www.pec.ha.osd.mil/2003_PEC_Conference/PEC_conference_2003.htm:

- **DoD Pharmacy Benefit Update**
  COL Daniel Remund MS, USA, Director, DoD Pharmacoeconomic Center

Excellent Quote of the Month

" MTFs will not have to conduct a massive therapeutic interchange program to switch patients to a different PPI."

Page 3

PEC Update Information

Subscribing

Would you like to receive the e-mail newsletter direct to your Inbox? Let us know by e-mailing Carol Scott, the PEC secretary, at carol.scott@amedd.army.mil.

Editors' E-mails

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Submitting Articles

Do you have an article you'd like to see published in the *PEC Update*? Just send CAPT Torkildson or Shana Trice an e-mail, or call the PEC at DSN 421-1271, Commercial (210) 295-1271.

- **An Introduction to Evidence Based Medicine: Resource Handout**
  CDR Ken Yew, MC, USN, Bureau of Medicine and Surgery
- **Practical Applications of Pharmacoepidemiology: Exercise**
  CDR Denise Graham, MS, USN, DoD Pharmacoeconomic Center
- **Basic Concepts of Outcomes Measurement**
  LtCol David Bennett, BSC, USAF, DoD Pharmacoeconomic Center
- **Preventing Adverse Drug Reactions**
  LTC(P) George Giacoppe, Madigan Army Medical Center
- **Research Funding Opportunities in the Department of Defense**
  LTC Stacey Young-McCaughan AN, USA, Chief, Outcomes Management, U.S. Army Medical Command

Publication Schedule

The *PEC Update* is published 10 times per year (monthly except July and December. On the grounds that no one is paying much attention those months, anyway...).

Our Disclaimer

The opinions expressed in this work are the views of the author(s), and do not necessarily reflect the views of the Department of Defense, the Army, Navy, Air Force, or the TRICARE Management Activity. Information presented in this work is meant for academic and educational purposes only. It is not intended nor should it be used as the definitive reference for the treatment or prophylaxis of various diseases. Use of specific product brand names are for identification purposes only unless otherwise indicated.

PEC Update Home
PEC Home

1 Next Page

PRINT VERSION (pdf file - requires Adobe Acrobat)

PEC Update Home
PEC Home

The Department of Defense Pharmacoeconomic Center

PEC UPDATE

February 2003, Vol. 03, Issue 4, www.pec.ha.osd.mil

EDITORIAL

Previous Page 2 Next Page

Thoughts From the TRICARE Conference, Among Other Things

CAPT Joe Torkildson, MC, USN
Director, Clinical Operations Division
DoD Pharmacoeconomic Center

Editors' Letters

Please send your letters to the editors to Dr. Torkildson at Joseph.Torkildson@amedd.army.mil

I was unusually uncomfortable the past month, ever since my last editorial. Despite the kind comments I received, I continued to have this nagging feeling that I left out a crucial part of the message. Last week I finally figured out what it was.

I had the pleasure (despite the weather) of attending the TRICARE Conference from 27-30 January in Washington DC. This was my third consecutive TRICARE Conference, and I can tell you they have all been quite different. In 2001 the atmosphere was almost giddy with celebration as people reflected on the tremendous improvements that had been made in the areas of claims processing, customer satisfaction, and benefit provision (with the upcoming initiation of TRICARE Senior Pharmacy and TRICARE For Life). The atmosphere last year was starkly different. With the country and our military services still reeling from the attack of September 11th, there was an eerie mix of courage, fear, uncertainty, and restless energy as the focus of the organization slowly moved from the almost total interest in the managed care mission to a renewed appreciation for the real reason we get up every morning and put on a uniform.

This year the atmosphere was again very different. The courage and uncertainty were still very evident. I could sense, though, that much of the fear had been replaced by a quiet confidence: confidence in the plan that had been developed by our leadership, and confidence that we had the skills and the energy to carry out that plan effectively. At the same time, the restless energy had been in large part replaced by a calm resolve that whatever we were called on to do as military health care providers (and I'm using the term 'provider' very generically here), we would carry on the proud tradition of those heroes in our medical community that have gone before us.

Then there were the presentations. For several hours each day, people stood up in breakout sessions and described problems they had encountered in healthcare delivery, and solutions that they had developed to effectively deal with these problems and improve the quality of the care provided to our beneficiaries. What was most exciting, though, was the fact that these weren't admin types or computer geeks sitting in cushy jobs in Washington (or San Antonio); they were largely front line people dealing with patients out in the trenches. These people somehow had adopted the beliefs that were so obviously in the air at the conference: 1) we have a problem; 2) we own the problem, it is ours to fix; 3) we have the capability to fix the problem; and 4) we will hold ourselves accountable for improving the conditions under which we work and live.

I was reflecting on this fact when it occurred to me what I had missed last month. I commented on the letter sent in by a senior provider who asserted that since the PEC did not come into MTFs and engage in counter-detailing activities (including bringing lunch), Barb's cautionary words about the detailing strategies of the pharmaceutical companies were without merit. This was a particularly pertinent issue at this individual's facility, as the facility commander had closed the dining hall previously as a cost-cutting measure, and now food brought in by reps during educational programs was perceived as the only way to easily get a decent meal. So the issue ultimately wasn't about making sound, cost-effective decisions about medication use, it was about meeting basic human needs. And the question being asked was not "How hard am I willing to work to feed myself?", but rather, "What are you going to do to help me solve my problem?"

Please understand that I'm not writing this to be critical. I think we've all been there, and in fact if I'm honest I have to admit that a big part of my decision to leave my last duty station and come to the PEC was the frustration I felt over the fact that other people weren't willing to see the same problems I saw with the facility and take the steps necessary to

correct them. At the time I just didn't get it. Getting it isn't easy. You have to believe that your problem is yours to own and fix. You have to believe that there is a solution; you just have to figure out what it is. This usually involves throwing out many of the ideas you've already come up with, and rethinking the conclusion you came to regarding the others that 'that will never work!'. I wonder if anyone at the facility above ever thought of going into the commander's office and saying, "My fellow providers and I have come up with the following initiative. If successful, it will decrease the cost of providing the level of care we are currently providing by $50,000/yr. Would you be willing to reopen our dining facility if we could pull this off?" I know, it's a crazy idea. It probably would never work. Then again, I saw a lot of projects presented last week that I never would have bet on either. Success is funny that way; it only shows up when the people doing the work believe it will come their way if they just put enough effort into it.

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PEC Update Home
PEC Home

Previous Page 2 **Next Page**

PRINT VERSION (pdf file - requires Adobe Acrobat)

PEC Update Home
PEC Home

The Department of Defense Pharmacoeconomic Center

PEC UPDATE

February 2003, Vol. 03, Issue 4, www.pec.ha.osd.mil

Update on DoD Procurement Initiatives for Pharmaceuticals:

Proton Pump Inhibitors & Much, Much More...

Previous Page 3 Next Page

LCDR Ted Briski, MSC, USN

**Navy Pharmacy Officer,
Director of Contracting Activities
DoD Pharmacoeconomic Center**

Name This Column!

LCDR Briski has promised us a regular column on DoD & DoD/VA procurement initiatives (contracts, blanket purchase agreements, etc.) Trouble is, we don't know what to call it. "Update on DoD Procurement Initiatives for Pharmaceuticals" seems a bit stuffy, but "Ted's Soapbox" may just be asking for trouble... Please send good (or amusing) suggestions to LCDR Briski at:

ted.briski@amedd.army.mil

Proton Pump Inhibitors...

The following is the text of a message sent out through the Pharmacy Consultants/Specialty Leaders on 26 Feb 2003

1. On December 12, 2002 Janssen Pharmaceutica Inc communicated its intention to raise the price of rabeprazole (Aciphex) to the DoD and VA from $0.22/unit to $0.35/unit, effective January 1, 2003, and then to their Federal Ceiling Price (FCP)(approximately $1.90/unit), effective April 1, 2003. Janssen also stated that the pricing decision was made by Eisai, the manufacturer of rabeprazole, and not by Janssen. In addition, in a

letter dated 17 January 2003, Janssen stated they could not supply rabeprazole to DoD at quantities much greater than DoD's current utilization. Eisai/Janssen's actions caused DoD/VA to enter into rigorous negotiations with all current manufacturers of branded PPIs. Three of the four current manufacturers of branded PPIs submitted proposals to the DoD/VA.

2. DoD and VA jointly agreed to accept a blanket purchase agreement (BPA) for rabeprazole proposed by Eisai/Janssen. The BPA will state that Eisai/Janssen will continue to provide rabeprazole at a price of $0.65 per tablet, effective April 1, 2003, and that the agreement will continue until VA and DoD have established a contract for a generic omeprazole. Acceptance of the rabeprazole BPA means that:

    - Rabeprazole will likely remain on the Basic Core Formulary for the foreseeable future
      MTFs will not have to conduct a massive therapeutic interchange program to switch patients to a different PPI.
      Rabeprazole will be available to MTFs at a much lower price ($.65) than previously expected ($1.90)

    - Limitations remain in effect regarding the amount of rabeprazole that MTFs can purchase. Eisai/Janssen is still unable to supply rabeprazole at quantities that exceed 105% of historical utilization levels.

3. The economics governing the PPI drug class have changed. The economic leverage obtainable by limiting formulary status to a single agent has significantly eroded. Due to the changing economics and the limitations on the supply of rabeprazole, the DoD and VA will consider adding a second PPI to their respective formularies. Questions or comments can be directed to CDR (sel) Ted Briski at (210) 295-2771, (DSN) 421-2771, or email Ted.Briski@amedd.army.mil.

...and Much, Much More

Numerous contract and incentive agreement initiatives have been underway over the last several months. A summary is provided below:

- **Leutinizing Hormone Receptor Releasing (LHRH) Agonist:** A joint DoD/VA contract was awarded to AstraZeneca for their goserelin acetate implant (Zoladex). The contract specifically solicited for an LHRH agonist used to treat prostate cancer. The contract will place Zoladex on the Basic Core Formulary (BCF) as the sole LHRH agonist. MTFs are not permitted to have competing LHRH agonists used to treat prostate cancer on their local formulary. The contract has not been loaded on the DSCP website yet, but should be available in the near future. Specific implementation guidance is currently being prepared.

- **Serotonin 5HT Receptor Antagonist (Triptans):** A joint DoD/VA contract was solicited for a workhorse triptan for preferred status on the BCF. The solicitation closed and offers were received. Currently the resolution of a protest is underway at the Government Accounting Office (GAO). An award is not expected until the May/June timeframe.

- **HMGs (Statins):** A Joint DoD/VA solicitation for a single high-potency HMG agent was released in January 2003. Proposals are due by the end of February. You can read the solicitation and amendment at www.eps.gov/spg/VA/VANAC/postdate_1.html

- **Angiotensin Receptor Blockers (ARBs):** A joint DoD/VA solicitation is being prepared. The language has been drafted. Editing and review underway.

- **Fluticasone Propionate (Flonase) Nasal Spray:** A Blanket purchase agreement (BPA) was signed on 1 January 2003. The agreement preserves the current pricing as long as market share is maintained above 90%. The product becomes approximately $1.00/inhaler more expensive if market share drops below 90 percent.

- **Levothyroxine (Synthroid):** New prices were loaded on 15 February. They are retroactive to 1 February 2003. The product will be approximately 2 to 3 time more expensive than before 1 January but substantially less than the Federal Supply Schedule prices

observed then. The prices should be visible at the prime vendor level on 1 March.

- **Oral fluroquinolones, ophthalmic prostaglandins, thiazolidinediones and bisphosphonates** continue to be in the contracting pipeline. More definitive information on the status of these classes will be provided in the next update.

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PEC Update Home
PEC Home

Previous Page 3 **Next Page**

PRINT VERSION (pdf file - requires Adobe Acrobat)

PEC Update Home
PEC Home

The Department of Defense Pharmacoeconomic Center

PEC UPDATE

February 2003, Vol. 03, Issue 4, www.pec.ha.osd.mil

Barb's Barbs

Previous Page 4 Next Page

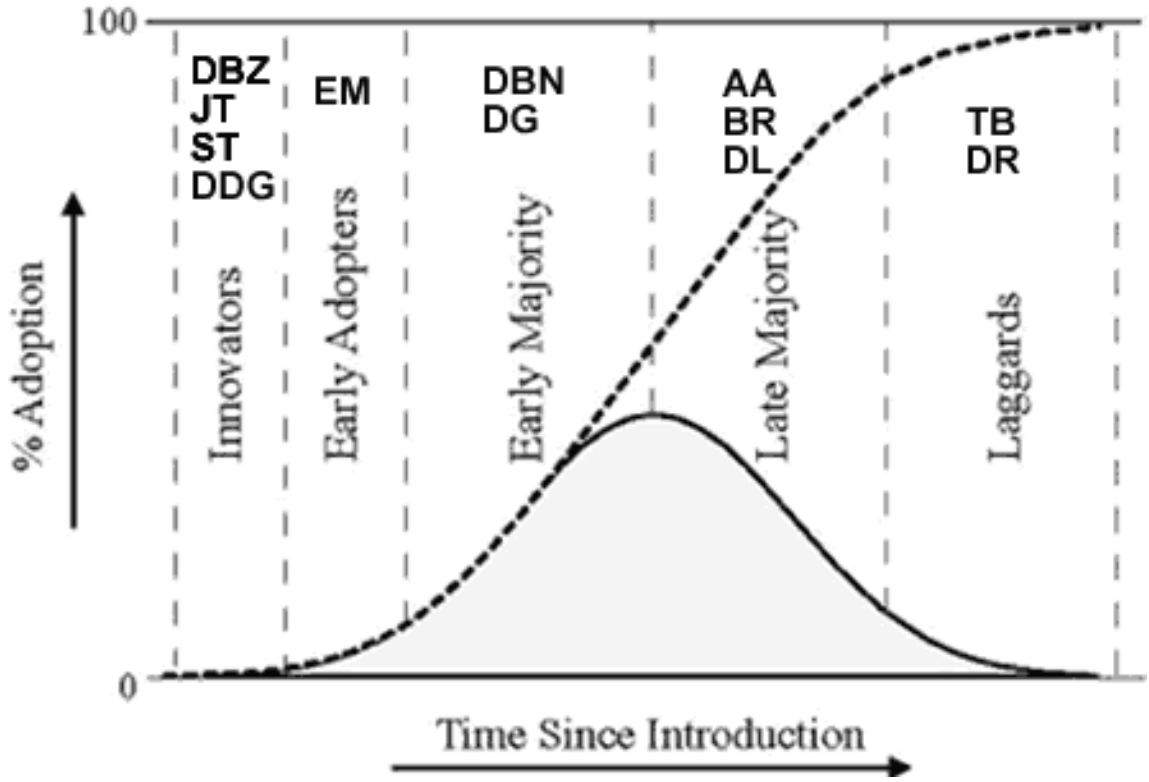
Technological Evaluation of the PEC Staff

LtCol Barbara Roach, USAF, MC
Air Force Medical Officer, DoD Pharmacoeconomic Center

For all you pharmaceutical reps who've mentioned that you live in fear of seeing yourself in one of my diatribes – I'm giving you the month off. Shana said I had to. I'll beat on us (the Pharmacoeconomic Center staff) for a change. Yeah – change- that's a good topic. How well do the docs and pharmacists here in the clinical heart of the PEC respond the need to change? After all, aren't I always whining about folks who don't consider new ideas? Let's look at a scale I've seen before, but didn't quite know how to fit into my babbling until I read a wonderfully written article on providers and technology on Medscape: *Achieving Clinician Buy-In to Technology* by Bryan Bergeron, MD (http://www.medscape.com/viewarticle/446224) .

Let's see how your PEC staff fares:

Adoption of New Technologies



You'll note that Dave Bretzke, CAPT Joe Torkildson, LTC Don DeGroff, and Shana Trice have always been exceptionally well qualified and continue to be innovative in the computer and technology geek arena. If Dave wasn't the techno-wiz that he is, there would be no PMART or RxNet and the folks at the PEc would still probably be trying to spell ARS Bridge (or M2 or whatever) correctly. If it weren't for Shana Trice's web-li-ness, there'd be no *PEC Update* (at least not in electronic form). She even **KNOWS** what HTML stands for and is one of those persons who have never forgotten anything she's seen in writing in her life. (I have a photographic memory too – unfortunately, I think it's a photo of a black hole in space.) [**Editor's Note**: Barb flatters me. She's probably trying to get me to **NOT** edit the *Barbs*...as unlikely as that is... ST)

Joe has just been making himself real smart this past year getting that medical MBA or whatever it is he disappears for on a routine basis. Yup, he'll be finishing that sucker up just in time to retire and run away and make some big bucks as a civilian. Then we'll be toast here as far as any actual business and marketing skills go. He and Dave probably really **could** shoot messages back and forth to each other via their Palm PC's, Pocket Pilots (or whatever those little computer things are called) during a staff meeting. Don DeGroff has to be in the innovator category for making PDTS actually work—remember all the folks a couple of years ago who said it could never possibly succeed?

Eugene Moore is another one of those Pharm.D.s who knows his way around a computer and knows what all those little icons are that Microsoft has splattered all over the top of the screen—and he even uses them. If he didn't, there would have been no one to handle the USPD database prior to the launch of PDTS.

(Of course there would be no USPD at all without CDR Mark Richerson, but since that wiener ditched us a couple years ago, we won't even mention him.)

Since LtCol Dave Bennett has only been here a few months I stuck him in the middle. He just finished one of those fancy advanced degree programs where you have to write a paper, so I know he's got at least a fair handle on technology. Of course, he forgot his wife's birthday last year and had the wrong month for one of his son's birthdays – but I think that's actually just a typical male flaw and not a technological problem. CDR Denise Graham actually knows which buttons to push to make a Power Point presentation presentable. She got to do that for Col Remund the first day she came to the PEC. They're both well versed in Outcomes Research and without them, the PEC wouldn't be moving forward into the area of useful outcomes measurements in conjunction with our VA counterparts.

The schizophrenic member of our group (who's already dumped us for the other side of the post) is COL Doreen Lounsbery. You can see I've placed her with Barb and Angela Allerman as far as technological expertise goes, but she could be anywhere. I think she was actually a spy placed here by LTG Peake since she came to the PEC in the AM and ran off to Great Plains in the afternoons. Well, it didn't work. She didn't discover anything, so now she's off to new adventures. Of course, the real reason she left each afternoon may have been that there were better munchies in that building on the other side of the parking lot than here at the PEC.

You may have noticed that, up to this point, all your PEC docs and pharmacists pretty much have been at a high functioning stage on the graph. There are a few at the PEC who have not quite revved up to speed in the technological arena, but you can definitely see progress. Since this may be a very sensitive topic for these folks, we'll just protect their identity by using initials or nicknames that you'd be hard pressed to figure out. T.B (or "Ted") appears to have actually gone backward on the technology scale since he/she arrived at the PEC. The reason for that could be that the demands of the PEC suck the very lifeblood out of you – but that's actually not the case here (though not through any lack of trying by co-workers or other contacts). T.B. (or "Ted B", as we'll refer to him to keep his identity undercover), doesn't really need technological expertise. The skills needed here are those of negotiation, an understanding of DoD's goofy contracting constraints, and a good poker face. If it weren't for "Teb B", someone else would have to figure out how to plead with the pharmaceutical companies for price breaks on medications of marginal clinical benefit. (Sorry, Shana, my fingers typed that all by themselves.)

You'll note that two staff members have elevated their standing on the bell curve above laggard level. Yes, "Ang" and "Barb" have learned how to do pivot

tables in Excel (a fact that still makes my palms break out in a sweat), but continue to curse at their laptops and will not likely move much higher on the curve for the moment. But that's okay. Where would the MTFs be without the worker bees at the PEC that do a lot of the clinical assessment for the DoD P&T Committee? (That's a rhetorical question. Don't you even **DARE** answer what I think you're thinking.)

Then lastly, but not leastly, there's some guy/gal named "Dan" who's stuck at the far end of the bell curve (and may be there for life). Definitely **NOT** a techno-wiz (if you change his/her screen saver he/she doesn't know how to make the old picture come back.) [**Editor's Note:** So now we know how **THAT** happens.] Definitely **NOT** beaming messages across the table with a Blackberry (he can't figure out how to use the cell phone his wife gave him yet). Definitely **NOT** adept at all the various software programs and databases we have access to (hasn't even taken the Business Objects course). **BUT**, without "Dan" this place would definitely **NOT** be an organization capable of helping DoD make cost-effective determinations. The PEC would definitely **NOT** be as coherent and congenial a place to work as it is now. And I personally dread the day he retires. (That probably sounds mushy, but it isn't. I just hate getting used to a new person who might actually think they're in charge of something here. We all know the secretary really runs the place.)

One addition that doesn't even fit on the graph is the "lower than laggard" community. One of my favorite Navy targets, CDR Mark Brouker, fits here. I sent out an e-mail message to the Navy Pharmacy Chiefs yesterday and his name was on my list for his facility. I get a lovely message back as follows: "Dear Barb, How are things going? Please take my name off your list and replace it with XXX YYYY. Mark." No e-mail address. No phone number. He's just as easy to torture now that he's not at the PEC as when he was here. Thanks, man. Dan is happy now that someone is below him in technology-land. (But no one can write a FIT report like Brouker, so he does excel in other areas.)

This was, of course, a real long-winded way to encourage you to increase your use of technology in your daily patient care. You can start by going to RxNet and providing input on any of the current topics we could use your two cents on. You can even initiate a topic. Just go to **www.dodrxnet.org** a nd register. Check off the topics of conversation you'd like to follow in the subscription section and then whenever someone posts (types some verbiage) in that topic, you get it automatically in your email. You don't have to go to the website again (unless you want to). Be a part of the decision-making process with the DoD P&T Committee. My distribution e-mail list bites.

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PEC Update Home
PEC Home

Previous Page  **Next Page**

PRINT VERSION (pdf file - requires Adobe Acrobat)

PEC Update Home
PEC Home

The Department of Defense Pharmacoeconomic Center

PEC UPDATE

February 2003, Vol. 03, Issue 4, www.pec.ha.osd.mil

New Drug Watch

Previous Page 5 Next Page

Angela Allerman
Clinical Pharmacy Specialist
DoD Pharmacoeconomic Center

This month: a new triptan (there are now seven), a new subcutaneous TNF inhibitor for rheumatoid arthritis, a new IV/IM biologic for severe psoriasis, a second testosterone gel product for hypogonadism, and a few new extended release formulations. Also: an insulin pen for kids, an OTC HbA1c testing device, and a number of new indications for existing drugs.

On the guideline front, we have the first evidence-based guidelines for lung cancer from the American College of Chest Physicians; guidelines for non-occupational post-exposure prophylaxis of HIV from the State of Rhode Island, the first Centers for Disease Control and Research (CDC) recommendations for adult immunizations, and the CDC's comprehensive smallpox vaccination website. Also: the recently-halted SMART Trial (Salmeterol Multi-Center Asthma Research Trial), the Food and Drug Administration (FDA's) website on drug shortages, and recommendations for preventing medications errors in children from the U.S. Pharmacopeia.

Quick Links

- Newly Approved Drugs
- Orphan Drugs
- New Generics
- New Medical Devices
- New Indications
- New Guidelines
- Clinical Trials in the News
- Drug Shortages
- Medication Errors

Newly Approved Drugs

Neurology

Eletriptan (Relpax; Pfizer) is the 7th (!) triptan to enter the market. Eletriptan received final approval in Dec 2002 for the treatment of acute migraine. Available tablet sizes: 20, 40, and 80 mg.

Psychiatry

A once-daily formulation of **alprazolam (Xanax XR; Pharmacia)** received FDA approval for panic disorder on Jan 17, 2003. Tablets are available in 0.5, 1, 2, and 3 mg strengths.

Ophthalmology

Cyclosporine ophthalmic emulsion 0.05% (Restasis; Allergan) has been approved to increase tear production in patients with suppressed tear production from keratoconjunctivitis sicca. A launch date has not yet been set.

Rheumatology

Adalimumab (Humira; Abbott) injection is a new tumor necrosis factor (TNF) inhibitor for the treatment of rheumatoid arthritis. The specific labeling is for "reducing the signs and symptoms and inhibiting the progression of structural damage in adults with moderately to severely active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDS)." Adalimumab is administered as a 40-mg subcutaneous injection every other week. Supply problems are not anticipated with this product. (**Editor's Note:** Supply problems with etanercept (Enbrel) appear to have resolved. Look for discontinuation of enrollment requirements for etanercept in the near future.] Labeling for adalimumab contains the same bolded warning for serious infections and sepsis as other TNF inhibitors.

Infectious Disease

Ciprofloxacin extended release (Cipro XR; Bayer) tablets are

approved in a 3-day regimen of 500 mg QD to treat uncomplicated UTI caused by *E. coli*, *Proteus*, *Enterococcus*, and *Staph*. species. This is a narrower indication than the immediate release ciprofloxacin formulation.

Stavudine extended release (Zerit XR; BMS) capsules are available in 37.5-, 5-0, 75-, and 100-mg strengths for treating HIV-1 infection in adults as part of a combination regimen.

Dermatology

Alefacept (Amevive; Biogen) injection is the first biologic approved for treating moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. CD4+ and CD8+ T-lymphocyte counts are reduced in a dose dependent manner via alefacept binding to the lymphocyte antigen, CD2, and inhibiting leukocyte function antigen-3 (LFA-3)/CD2 interaction. Alefacept is administered as a weekly IV bolus or IM injection for 12 weeks; weekly monitoring of CD4+ counts are recommended due to immunosuppressive effects. **Note:** The TNF-inhibitors infliximab (Remicade), etanercept (Enbrel), and adalimumab (Humira) are all in phase III/II studies for the treatment of psoriasis. Another injectable monoclonal antibody for psoriasis, efalizumab (Raptiva; Genentech/Xoma), is also in the pipeline.

Biovail will be launching **acyclovir cream 5% (Zovirax)** in 2003. It is indicated for treatment of recurrent herpes labialis. Topical acyclovir was previously available as a 5% ointment.

Azelaic acid gel 15% (Finacea; Berlex) is now approved for mild to moderate rosacea. This product is a slight modification of azelaic acid 20% cream (Fineven; Berlex) which is approved for acne.

Men's Health

Testosterone gel 1% (Testim; Auxilium) has been approved

by the FDA for the topical treatment of primary hypogonadism or hypogonadotropic hypogonadism. This is the second testosterone gel available (Androgel by Unimed/Solvay was the first.) The FDA Orange book has designated both products as reference listed drugs; they are not generically equivalent.

Orphan Drugs

Baxter and Alpha Therapeutics will be marketing **human alpha-1 proteinase inhibitor (Aralast)** for the treatment of hereditary emphysema / alpha 1 antitrypsin deficiency. The drug is administered as a weekly IV infusion. Existing lung disease is not reversed with treatment, but further damage is prevented. Approximately 5000 patients are diagnosed with alpha-1 proteinase deficiency in the U.S.

New Generics

Geneva Generics has received marketing approval for another **OTC loratadine** tablet. A launch date has not been publicized.

Two isotretinoin generics AB-rated to Roche's Accutane are now approved; **Bertek's Amnesteem**, (**www.amnesteem.com**) and **Ranbaxy's Sotret** (**www.ranbaxyusa.com**). Both manufacturer's have satisfied the FDA requirements for implementing a controlled distribution system to reduce the risk of teratogenicity and psychiatric reactions. Like Accutane, both generic products require a sticker on the prescription prior to dispensing. Bertek's monitoring program is called "System to Prevent Isotretinoin-Related Issues of Teratogenicity"(SPIRIT) while Ranbaxy's is called the "Isotretinoin Medication Program Alerting you to the Risks of Teratogenicity" (IMPART). Both programs are similar to Roche's "SMART" program for Accutane, and all three products will have assessment of the success of pregnancy avoidance programs performed at Boston University's Slone Epidemiology Center. Barr also has a generic isotretinoin pending at the FDA.

New Medical Devices

An **insulin pen targeted for children, NovoNordisk's NovoPen Junior,** is now available. The delivery system allows for half-unit dosing increments and can administer 1 to 35 units.

An **OTC test for hemoglobin A1C (Metrika A1C Now; Metrika Inc)** has been approved by the FDA. The product was previously only available with a prescription. The device is the size of a pager, and requires a finger stick; results are available in 8 minutes.

New Indications

Labeling for **fluoxetine (Prozac; Lilly)** now includes an indication for treating children and adolescents aged 7 to 17 years for major depressive disorder and obsessive compulsive disorder. Results from two placebo-controlled trials were used to obtain the new labeling. Fluoxetine is the first SSRI with a pediatric labeling.

Montelukast (Singulair; Merck) tablets received FDA approval for relief of symptoms of allergic rhinitis in patients 2 years of age or older, in January 2003. The new indication expands the previous labeling for asthma.

Lamotrigine tablets (Lamictal; GlaxoSmithKline) received an expanded indication for use in children as young as age two, as "add-on" therapy for partial seizures. Lamotrigine was previously approved for use in adults with partial seizures, and for children with Lennox-Gastaut Syndrome-associated generalized seizures. Serious rash reactions, including Stevens Johnson Syndrome, have occurred in pediatric patients taking lamotrigine.

Linezolid injection, tablets and oral suspension (Zyvox; Pharmacia) are now approved for pediatric use in children aged birth to 17 years, for VRE and other gram-positive infections.

The FDA has approved **imatinib mesylate (Gleevec;**

Novartis) tablets as first-line therapy for chronic myeloid leukemia (CML). It was previously approved as 2nd-line therapy for CML.

Divalproex sodium extended release (Depakote ER; Abbott) 500 mg tablets have gained approval as once-daily monotherapy and adjunctive therapy for adults with complex partial seizures. This extended release dosage form was previously limited to use for migraine prophylaxis in adults.

New Guidelines

The **American College of Chest Physicians (ACCP)** has published the **first evidence-based guidelines for lung cancer** [CHEST January, 2003;123(Suppl 1):1S-337S]**.** A multi-disciplinary approach is recommended, with individual chapters discussing prevention, detection, diagnosis, staging, treatment, and palliative care. The most controversial aspect of these guidelines is the recommendation to not use CT scans for screening, due to the lack of evidence for improved outcomes or survival. The key aspect of prevention is smoking cessation. ACCP anticipates updating the guidelines on a routine basis. The guidelines are available by calling ACCP at 800-343-2227, or on the Web at **www.chestnet.org** (registration may be required).

The **State of Rhode Island** has developed **guidelines for non-occupational post-exposure prophylaxis of HIV**. The document, entitled "Non-occupational Human Immunodeficiency Virus Post-exposure Prophylaxis Guidelines for Rhode Island Healthcare Practitioners," deals with such situations such as potential HIV exposure following sexual assault, needlesticks from syringes left in garbage cans, or condom breakage during sex. The 30-page document is available on the web site from the Rhode Island Department of Health (**www.healthri.org/media/020925a.htm**) and the Brown University AIDS Program (**www.brown.edu/Departments/BRUNAP/backnpep.htm)**.

Recommendations for adult immunizations are available from the **CDC** at **www.cdc.gov/nip/recs/adult-schedule.pdf**.

This is the first time that the CDC has addressed vaccinations in adults. The document includes a color-coded table for the adult vaccines (tetanus/diphtheria, influenza, pneumococcal, hepatitis A, hepatitis B, measles/mumps/rubella, varicella, and meningococcal). Immunizations in adults with medical conditions such as pregnancy, HIV, diabetes, heart disease, cancer, and renal failure are also addressed.

The **CDC** has also developed a **comprehensive website targeted for healthcare practitioners dealing with smallpox vaccination**: **www.bt.cdc.gov/agent/smallpox/index.asp**.

Clinical Trials in the News

A large safety trial with **salmeterol xinafoate** has been halted due to concerns of increased risks for life-threatening asthma episodes or asthma-related deaths in African-Americans or patients not receiving inhaled corticosteroids. Approximately 26,000 subjects out of the expected 60,000 patients were enrolled in the SMART trial (Salmeterol Multi-Center Asthma Research Trial), which was initiated in 1996. The study details have not been released, but the FDA is expected to meet with the manufacturer to obtain more information. The FDA has stressed that the serious adverse events reported in the interim analysis were rare, and the benefits of salmeterol outweigh the risks for asthmatics. A talk paper that discusses the trial is available on the FDA website: **www.fda.gov/bbs/topics/ANSWERS/2003/ANS01192.html.**

Drug Shortages

The FDA web site on drug shortages (**www.fda.gov/cder/drug/shortages**) contains useful information for pharmacists, including product shortages, reasons for the shortage, products with limited distribution, discontinued drugs, and practical steps for practitioners facing shortage situations. A link to **the American Society of Health-System Pharmacists (ASHP) Drug Shortages Resource Center website** (**http://www.ashp.com/shortage/index.cfm**) is also included

on the FDA site .

Medication Errors

Prevention of Medication Errors in Children is one topic discussed by the **US Pharmacopeia (USP)**. Data from actual medical error reports was used to compile the recommendations, which are available by sending an email request to **mediarelations@usp.org** (consult the USP website at **www.usp.org** for a brief summary). The recommendations discuss potential errors that can occur in the areas of compounding, packaging, storing, prescribing, and administrating medications for children. Key aspects of the recommendations include having a pharmacist compound any special medications for children, not using terminal ("trailing") decimal points ("1 mg" **NOT** "1.0 mg"), and dispensing liquids with an appropriate measuring device.

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PEC Update Home
PEC Home

Previous Page 5 **Next Page**

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PEC Update Home
PEC Home

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February 2003, Vol. 03, Issue 4, www.pec.ha.osd.mil

PDTS Corner

Previous Page 6

Update on the Pharmacy Data Transaction Service

Prescription Workload Trends

By COL (Ret) Roger Williams, PDTS CSSC, Clinical Support Supervisor

Editor's Note: The CSSC is reassessing the routine content of the PDTS Corner section of the *PEC Update*. What would **YOU** like to see (or not see)?

Please send suggestions, comments, and wild praise to Roger Williams at:

Roger.Williams2@amedd.army.mil

Those of us who have been involved with DoD Pharmacy operations over the years can recall anecdotal comments in regard to workload and wishing we had some way to forecast future demands. While some of us may have been successful in developing a means to track and monitor our local workload, up to now there has been no way for management to monitor workload at a global level and trend it over time. Well, that is now a thing of the past, thanks to the Pharmacy Data Transaction Service (PDTS).

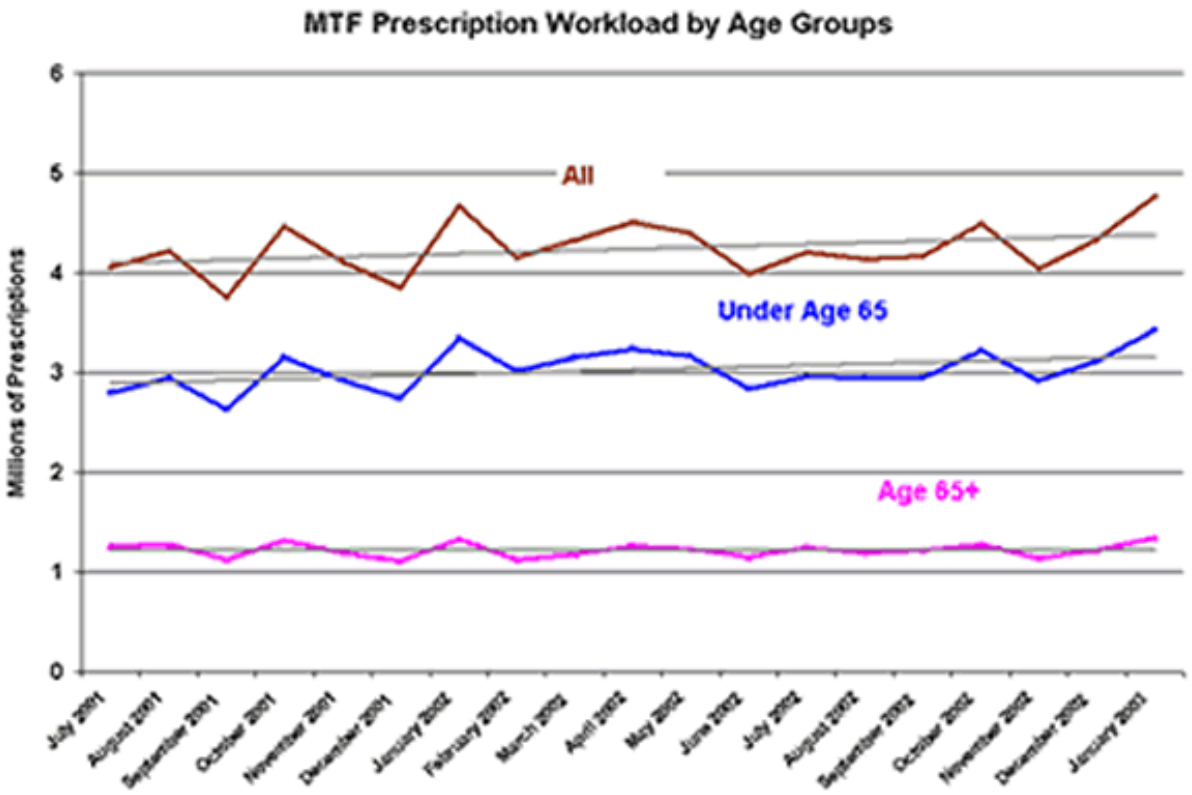
Since the last MTF came on line with PDTS in July 2001, we have been monitoring the prescription workload from all three DoD points of service (MTFs, retail network pharmacies and mail order). The data has been presented in various reports on a weekly or monthly basis, broken out by point of service or by branch of Service. For all practical purposes, the group possibilities are limitless. We could even trend the workload by TRICARE Region, Army Regional Medical Commands or Air Force Major Commands. (Sorry, I know of no Navy equivalent to the latter two.)

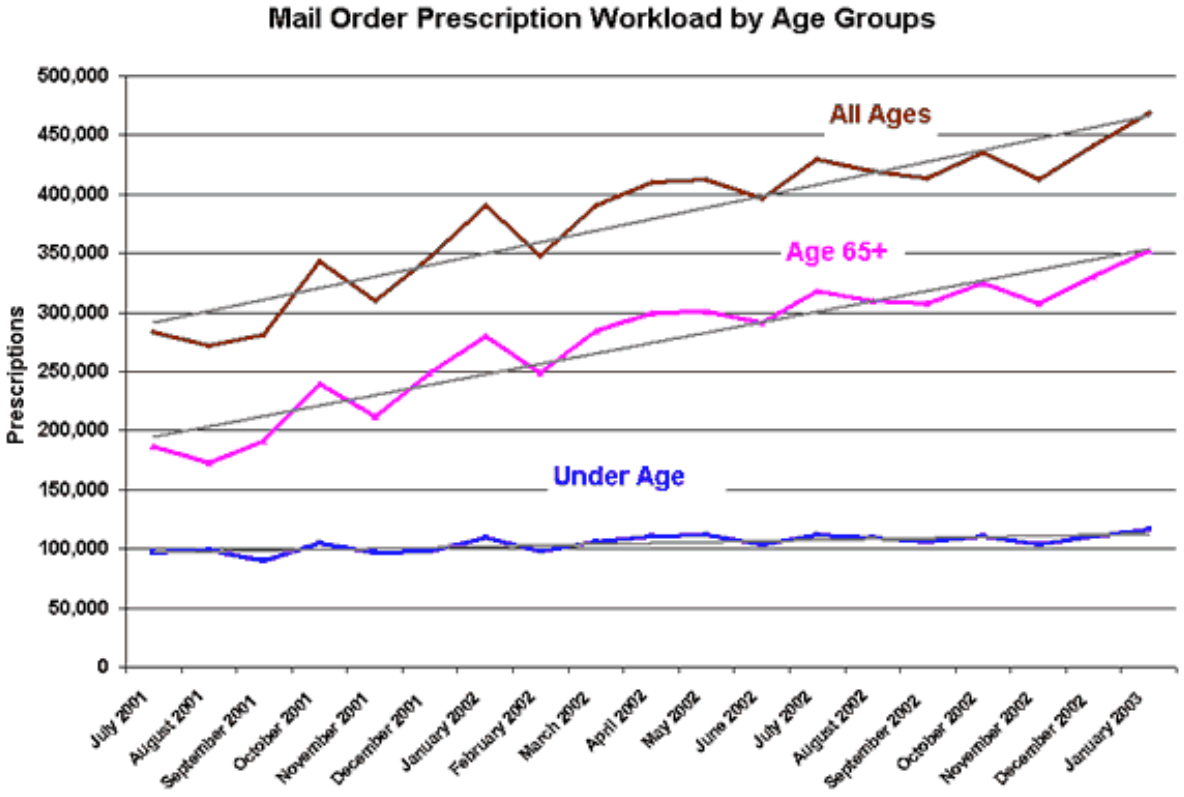
From the global perspective, it is no secret that workload in the retail network and mail order points of service have been on the rise. In mail order, this growth can basically be attributed to the advent of the TRICARE Senior Pharmacy benefit that went into effect in April 2001; beneficiaries age 65 or older now make up over 75% of the mail order workload. However, the growth in the retail networks has been somewhat different. Here, the workload in both age groups, under 65 and 65 or older, has been on a steady rise, with utilization by age 65 or older beneficiaries slowly overtaking under 65 beneficiaries. The beneficiary mix in the retail network is now about 55% age 65 or older beneficiaries and 45% under 65 beneficiaries.

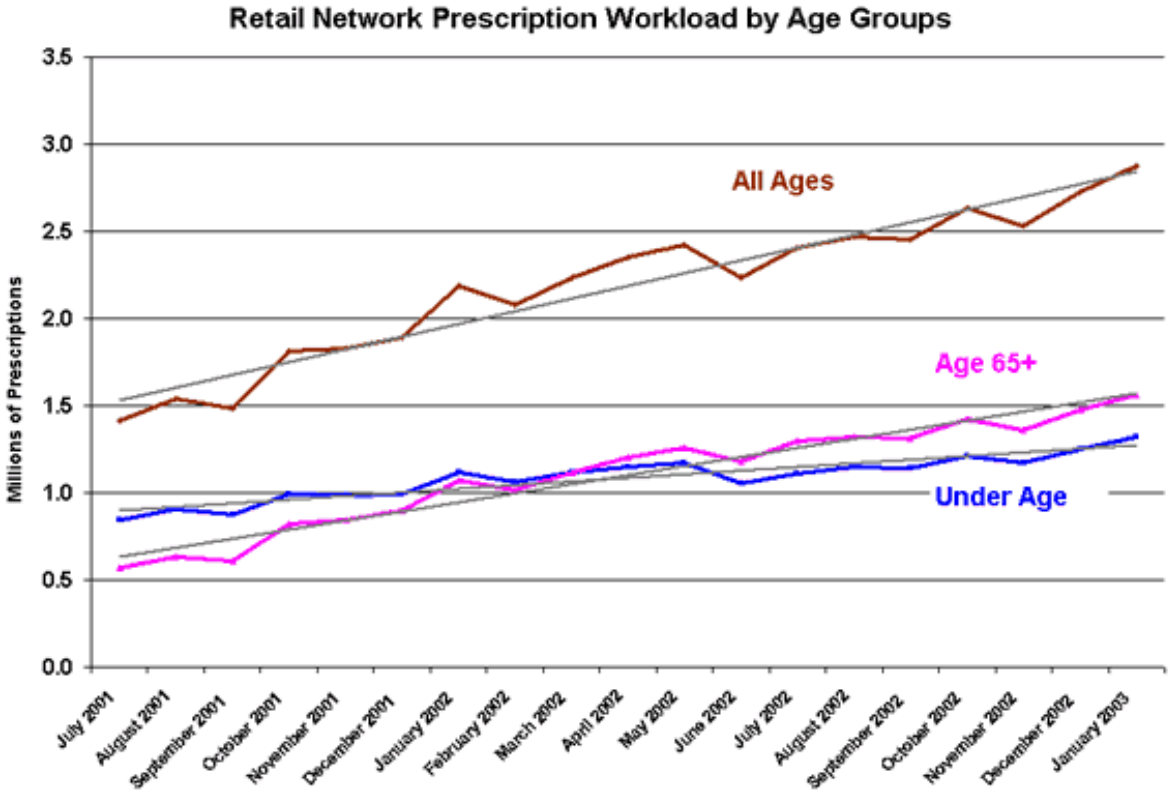
What many may not realize is that the overall MTF workload is also on an upward slope. This increase appears to be coming from the under 65 population as utilization by age 65 or older beneficiaries seem to be holding steady. While it's true that the MTF increase is not as significant as in the other two points of service, I believe the mere fact that the workload is not declining is significant in itself. See below to see trend lines for each point of service.

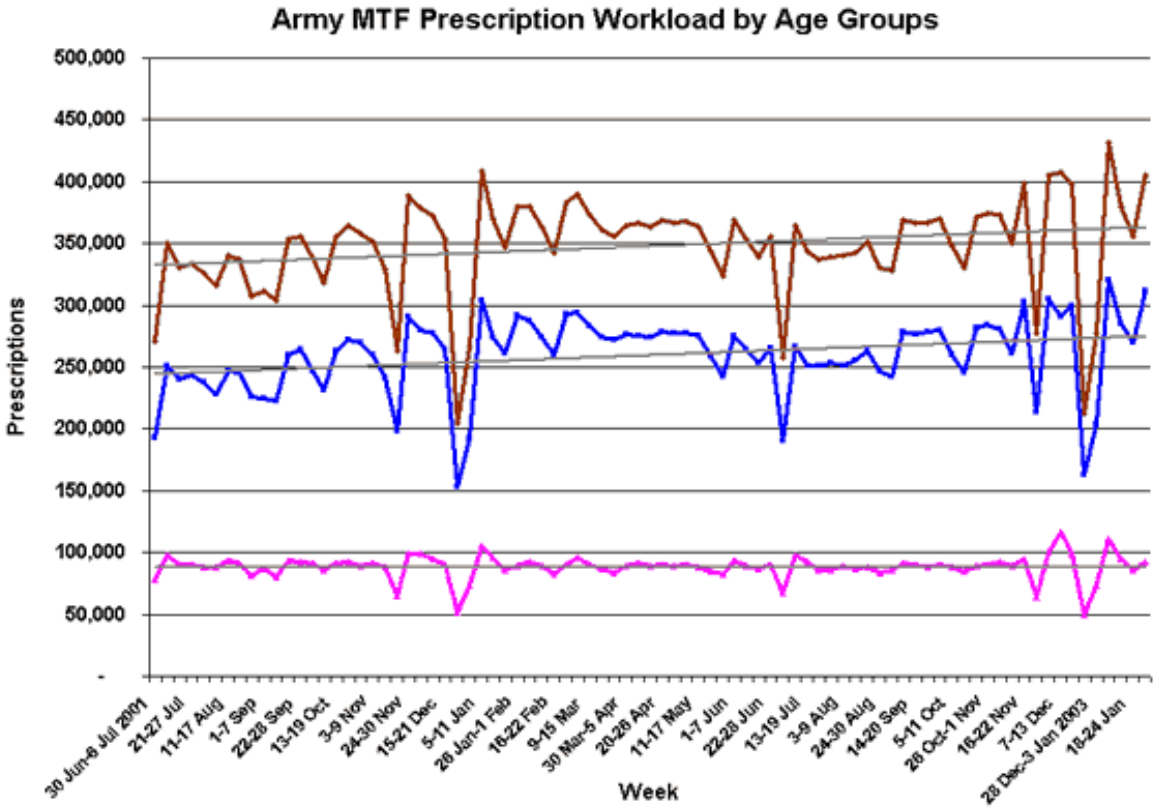
When you look at the workload of the individual branches of Service, it is interesting to note that each one of them mirrors the trend of the MTFs as a whole. Each Service shows a small increase in their respective workloads, basically in the under-65 beneficiary population while their age 65 and older workload holds steady. All three Services appear to have the same peaks and valleys, reacting the same to holidays and seasonal trends. About the only difference is in the actual numbers.

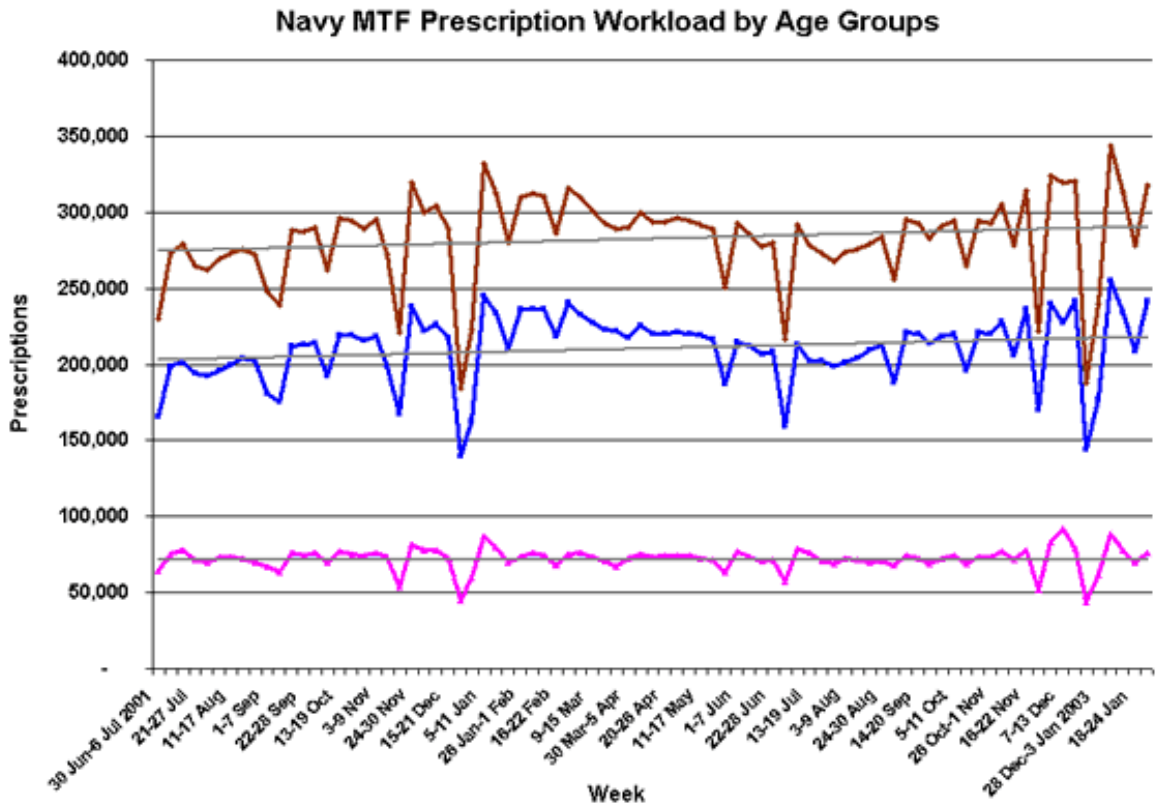
Now what does all this mean? That, I believe, is a topic for another *PEC Update*.

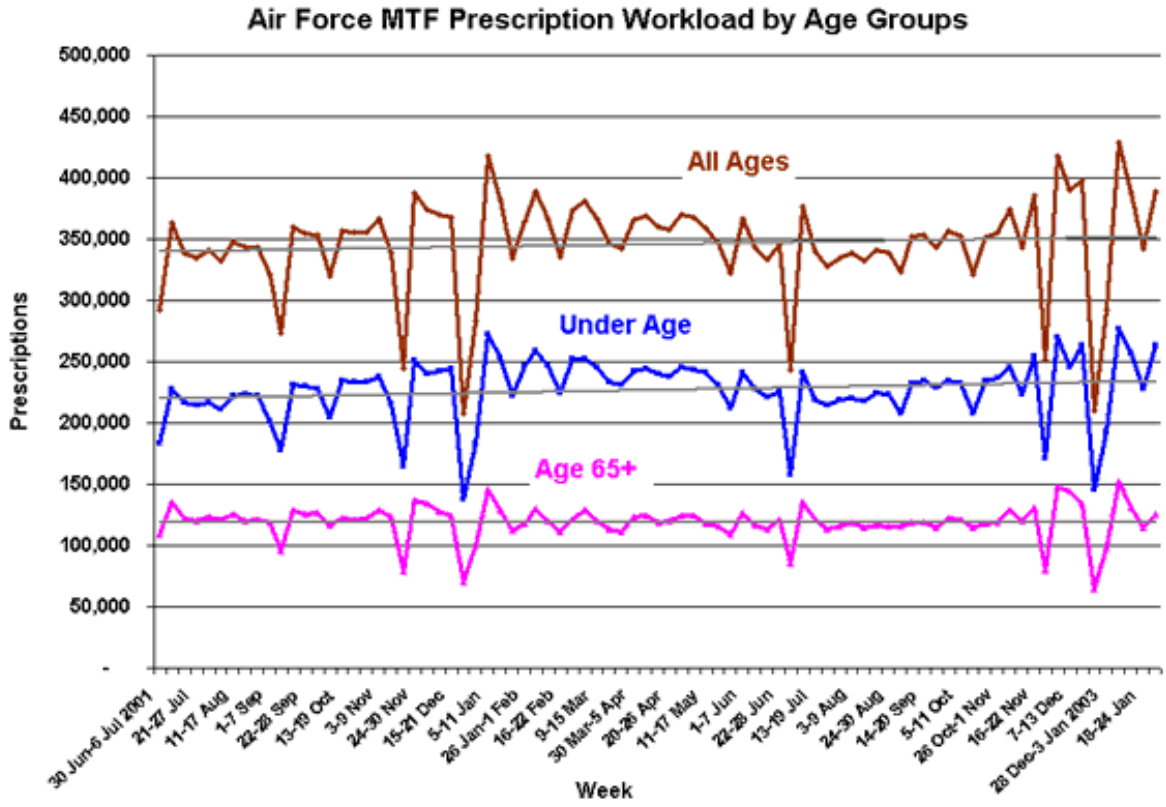





Retail Network Prescription Workload by Age Groups
Millions of Prescriptions
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
All Ages
Age 65+
Under Age
July 2001
August 2001
September 2001
October 2001
November 2001
December 2001
January 2002
February 2002
March 2002
April 2002
May 2002
June 2002
July 2002
August 2002
September 2002
October 2002
November 2002
December 2002
January 2003


Army MTF Prescription Workload by Age Groups
Prescriptions
500,000
450,000
400,000
350,000
300,000
250,000
200,000
150,000
100,000
50,000
-
30 Jun-6 Jul 2001
21-27 Jul
11-17 Aug
1-7 Sep
22-28 Sep
13-19 Oct
3-9 Nov
24-30 Nov
15-21 Dec
5-11 Jan
26 Jan-1 Feb
16-22 Feb
9-15 Mar
30 Mar-5 Apr
20-26 Apr
11-17 May
1-7 Jun
22-28 Jun
13-19 Jul
3-9 Aug
24-30 Aug
14-20 Sep
5-11 Oct
26 Oct-1 Nov
16-22 Nov
7-13 Dec
28 Dec-3 Jan 2003
18-24 Jan
Week


Navy MTF Prescription Workload by Age Groups
Prescriptions
400,000
350,000
300,000
250,000
200,000
150,000
100,000
50,000
-
30 Jun-6 Jul 2001
21-27 Jul
11-17 Aug
1-7 Sep
22-28 Sep
13-19 Oct
3-9 Nov
24-30 Nov
15-21 Dec
5-11 Jan
26 Jan-1 Feb
16-22 Feb
9-15 Mar
30 Mar-5 Apr
20-26 Apr
11-17 May
1-7 Jun
22-28 Jun
13-19 Jul
3-9 Aug
24-30 Aug
14-20 Sep
5-11 Oct
26 Oct-1 Nov
16-22 Nov
7-13 Dec
28 Dec-3 Jan 2003
18-24 Jan
Week


Air Force MTF Prescription Workload by Age Groups
Prescriptions
500,000
450,000
400,000
350,000
300,000
250,000
200,000
150,000
100,000
50,000
-
All Ages
Under Age
Age 65+
30 Jun-6 Jul 2001
21-27 Jul
11-17 Aug
1-7 Sep
22-28 Sep
13-19 Oct
3-9 Nov
24-30 Nov
15-21 Dec
5-11 Jan
26 Jan-1 Feb
16-22 Feb
9-15 Mar
30 Mar-5 Apr
20-26 Apr
11-17 May
1-7 Jun
22-28 Jun
13-19 Jul
3-9 Aug
24-30 Aug
14-20 Sep
5-11 Oct
26 Oct-1 Nov
16-22 Nov
7-13 Dec
28 Dec-3 Jan 2003
18-24 Jan
Week

The PDTS Customer Service Support Center

The PDTS CSSC strives to provide world-class customer support to all Military Health System users while enhancing the operational effectiveness and ensuring the quality of information maintained within the Pharmacy Data Transaction Service. The PDTS CSSC comprises the Pharmacy Benefit Operations Division of the PEC and is co-located with the Clinical Operations Division of the PEC at Ft. Sam Houston, TX.

The PDTS CSSC has an e-mail address for questions, comments, concerns, or report requests:

PDTS@cen.amedd.army.mil

Drop us an e-mail! We will respond via e-mail or call you within 1 business day.

Or call the PDTS CSSC at:

- DSN: 471-8274
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  (1-866-ASK4PEC)
- Local commercial (San Antonio):
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Need more information?

Many materials pertaining to PDTS, including trouble call procedures, the PDTS Report Request Form, business rules, and interchange control documents (ICDs), are available in the PDTS section of the PEC website. Just go to **www.pec.ha.osd.mil/pdts/pdts_documents.htm** and browse through the options on the left-hand navigation bar.

In addition, many articles on various aspects of PDTS and the PDTS CSSC have been published in recent issues of the *PEC Update*. Please visit the PEC Update page on the PEC website - **www.pec.ha.osd.mil/ac03000.htm** - for back issues.

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PEC Update Home
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Previous Page 6